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UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
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#44

Dominic M. Mezzapelle
Associate General Counsel-Patents
Bristol-Myers Squibb Company
345 Park Avenue
New York, NY 10154

Re: Patent Term Extension
Application for
U.S. Patent No. 4,978,655

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,978,655, which claims the human drug product ZERIT, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 189 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of November 16, 1994. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} \text{ (Testing Phase)} + \text{Approval Phase} \\ &= \frac{1}{2} (1,805 - 698) + 179 \\ &= 733 \text{ days}\end{aligned}$$

Since the regulatory review period began January 19, 1989, before the patent issued (December 18, 1990), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From January 19, 1989 to December 18, 1990 is 698 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period: $1,805 - 698 = 1,107$ days.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product (June 24, 1994) when added to the period of extension calculated above (733 days) cannot exceed fourteen years. The period of extension is thus limited to June 24, 2008, by operation of 35 U.S.C. § 156(c)(3). Since the original patent term of seventeen years (35 U.S.C. § 154) would expire on December 18, 2007, the period of extension is the number of days to extend the term of the patent from its expiration date to and including June 24, 2008, or 189 days.

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

A single request for reconsideration of this final determination as to the length of extension

of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 189 days.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

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|---------------------|--|
| U.S. Patent No.: | 4,978,655 |
| Granted: | December 18, 1990 |
| Applicant: | Tai-Shun Lin et al. |
| Owner of Record: | Yale University |
| Title: | USE OF 3'-DEOXYTHYMIDIN-2'-ENE (3'DEOXY-2',3'-DIDEHYDROTHYMIDINE) IN TREATING PATIENTS INFECTED WITH RETROVIRUSES |
| Classification: | 514/50 |
| Product Trade Name: | ZERIT |
| Term Extended: | 189 days |

Gerald A. Dost
Gerald A. Dost
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

(703) 305-9285

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fisher's Lane, Room 11-44
Rockville, MD 20857

RE: ZERIT
FDA Docket No.: 94E-0332